McCann, AmyArnold

TES Covance P.A #2 corresp.

From: Roethig, Hans
Sent: Tuesday, November 05, 2002 8:34 AM
To: Carchman, Loreen
Cc: Venable-Waple, Bristow (RD &E); McCann, AmyArnold
Subject: RE: Lab data specifications

Thank you, I am very happy if we get this moved forward.
Best regards
Hans

-----Original Message-----
From: Carchman, Loreen
Sent: Monday, November 04, 2002 8:44 PM
To: Roethig, Hans
Cc: Venable-Waple, Bristow (RD &E); Arnold, Amy
Subject: Fw: Lab data specifications

Hans,

Bristow is drating the NOTICE for Amy's review. This should be completed and mailed by the end of this week. If. You have any further questions, please let me know. Thanks,
---
-L

-----Original Message-----
From: McCann, AmyArnold <Amy.Arnold@us.pm.com>
To: McCann, AmyArnold <Amy.Arnold@us.pm.com>; Carchman, Loreen <Loreen.L.Carchman@pmusa.com>
CC: King, Valerie A. <Valerie.A.King@pmusa.com>; Venable-Waple, Bristow (RD &E) <M.Bristow.Venable-Waple@pmusa.com>
Sent: Mon Nov 04 18:20:30 2002
Subject: RE: Lab data specifications

Loreen:

Hans stopped by today asking about the situation below. I told him what I told you and he asked that I follow up on the status. Can you let him know the status. Also, let me know if you need me to review the letter or have any additional questions.

Thanks.

-----Original Message-----
From: Arnold, Amy
Sent: Thursday, October 31, 2002 8:24 AM
To: Carchman, Loreen
Cc: King, Valerie A.; Venable-Waple, Bristow (RD &E)
Subject: RE: Lab data specifications

Loreen:

You can write a letter to Covance indicating that pursuant to P.A. #2 the letter serves to notify Covance that MDS is a data management vendor authorized to receive the e-Trials information and that Covance should facilitate the transfer of data. The letter should go to Mary. I suggest that it come under Hans' signature, but it is not required if Hans is not available. Once the letter is prepared, I will be happy to look at it.

Let me know if you have any additional questions.

Source: https://www.industrydocuments.ucsf.edu/docs/gtcj0001

-----Original Message-----
From: Carchman, Loreen
Sent: Wednesday, October 30, 2002 6:18 PM
To: Arnold, Amy
Cc: King, Valerie A.; Venable-Waple, Bristow (RD &E)
Subject: Re: Lab data specifications

Amy, Thanks for your response. One question, when you say "All you need to do is indicate....". How do I do that? Via a NOTICE?? I guess I've never done this before and need a little guidance.

Also, I will ask Val to check on the Confidentiality Agreement between the two.

Thanks,

-L

-----Original Message-----
From: Arnold, Amy <Amy.Arnold@us.pm.com>
To: Carchman, Loreen <Loreen.L.Carchman@pmusa.com>
CC: Osborne, Kevin (PMMC Legal) <Kevin.Osborne@us.pm.com>; Venable-Waple, Bristow (RD &E) <M.Bristow.Venable-Waple@pmusa.com>
Sent: Wed Oct 30 16:42:10 2002
Subject: RE: Lab data specifications

Loreen:

Exhibit A to P.A. #2 states that Covance will use "[c]ommercially reasonable efforts . . . to facilitate the transfer of data by e-Trials including topography . . . to the data management vendor designated by the Company." The Master states that notices go to Mary Westrick at Covance.

All you need to do is indicate that MDS is one of the vendors we designate to receive the information.

I suggest that you also take the opportunity to confirm that Covance and e-Trials have the appropriate confidentiality agreement. There is a confidentiality agreement between PM USA and MDS.

Let me know if you have any questions.

-----Original Message-----
From: Carchman, Loreen
Sent: Wednesday, October 30, 2002 12:38 PM
To: Osborne, Kevin (PMMC Legal); Arnold, Amy
Cc: Venable-Waple, Bristow (RD &E)
Subject: FW: FW: Lab data specifications

Kevin/Amy,

Is this OK from a Legal perspective??? Thoughts???

Thanks,
-L

-----Original Message-----
From: Roethig, Hans
Sent: Tuesday, October 22, 2002 5:59 PM
To: King, Valerie A.
Cc: Carchman, Loreen; Venable-Waple, Bristow (RD &E); Oey, Jan
Subject: RE: FW: Lab data specifications

I share your view!

Source: https://www.industrydocuments.ucsf.edu/docs/gtcj0001

Perhaps Bristow my draft a letter when she is back.
Best regards
Hans

-----Original Message-----
From: King, Valerie A.
Sent: Tuesday, October 22, 2002 10:55 AM
To: Roethig, Hans
Subject: FW: FW: Lab data specifications

Hans:
Please see Jeff Milhone's note below. I believe that is consistent with your thinking.

If you agree, I think it would be most appropriate if the communication he references should come from you. Let me know your thoughts.

Thanks,
Valerie

-----Original Message-----
From: Jeffrey Milhone [SMTP:jeffrey.milhone@covance.com]
Sent: Tuesday, October 22, 2002 10:18 AM
To: Jill Schultz; Valerie.A.King@pmusa.com
Cc: jaredfreedberg@covance.com
Subject: Re: FW: Lab data specifications

It is my understanding that the scope of work for eTrials has not changed from what was first envisioned as they are merely transferring the data to MDS instead of Covance. The work that eTrials is doing is based on an approved subcontract and is ultimately covered as our subcontractor under Covance's agreement with Philip Morris. I believe all we need is something in writing from Philip Morris, a letter or formal email should suffice, referencing our contract and stating that we are authorized to share the information in question with MDS.

If you have any further concerns or wish to discuss it in more detail please feel free to contact me at (608) 242-2712 x2261.

>>> Jill Schultz 10/21/02 07:53PM >>>

Hi Valerie,

Just catching up on a few emails while I'm still away. I think a confidentiality agreement between etrials and MDS would be appropriate but there is no need for Master Agreement or Task Order.

Jeff, do you agree?

Jill

>>> <Valerie.A.King@pmusa.com> 10/18/02 01:30PM >>>
Hi Jill...I hope this finds you well after a great vacation.

I just wanted to follow-up with you on Hans' note below. I have been in discussions with the VP of contracts at MDS re the issue below. Hans was

under the impression that neither a confidentiality agreement nor a contract
would need to be established between etrials and MDS. I need to find out if
this is a correct understanding based on the existing agreement between etrials and Covance. Please let me know so that I can get back to MDS as

soon as possible.

Source: https://www.industrydocuments.ucsf.edu/docs/gtcj0001

Thanks,
Valerie

> -----Original Message-----
> From:Roethig, Hans
> Sent:Wednesday, October 16, 2002 5:29 PM
> To:'Jodi Pickering'; Steven.Zweig@mdsps.com ; Jill Schultz (E-mail)
> Cc:Dana Winsted; Anthony.Cavaliere@mdsps.com ; Bob.Lynch@mdsps.com ;
> Fang.Fan@mdsps.com ; kimberly.prchal@mdsps.com ; Robert.Earl@mdsps.com
;
> Nelson, Bettie L; Adams, Candace R.; Roethig, Hans; Oey, Jan; Sarkar,
> Mohamadi; Kinser, Robin D.; Feng, Shixia; King, Valerie A.
> Subject:RE: Lab data specifications
>
> There must be some misunderstanding jodi, please talk to Jill Schultz
from
> Covance. I do not think that any new agreement is necessary between
> e-trials and MDS. Your Covance agreement should cover these points.
> Best regards
> Hans J Roethig, MD, PhD, FCP, FFPM
> Director Clinical Evaluation
> Philip Morris USA
> 615 Maury Street
> Richmond, VA 23224
> Phone: (804) 274-3165
> Fax: (804) 274-2891
> Mobile phone: (804) 687-1655
> e-mail: hans-juergen.roethig@PMUSA.com
>
> -----Original Message-----
> From: Jodi Pickering [mailto:jodi.pickering@etrials.com]
> Sent: Monday, October 14, 2002 10:55 AM
> To: Steven.Zweig@mdsps.com
> Cc: Dana Winsted; Anthony.Cavaliere@mdsps.com ; Bob.Lynch@mdsps.com ;
> Fang.Fan@mdsps.com ; kimberly.prchal@mdsps.com ; Robert.Earl@mdsps.com
;
> bettie.l.nelson@pmusa.com ; candace.r.adams@pmusa.com ;
> Hans-Juergen.Roethig@pmusa.com ; Jan.Oey@pmusa.com ;
> mohamadi.sarkar@pmusa.com ; robin.d.kinser@pmusa.com ;
> Shixia.Feng@pmusa.com ; Valerie.A.King@pmusa.com
> Subject: RE: Lab data specifications
>
>
> Steven,
>
> As discussed, we will need to have at a minimum a Confidentiality
> Agreement in place prior to any information being transferred between
MDS
> and etrials. We also will need a Master Services Agreement as well as
a
> Task Order to accommodate for the transfer fees and the final database

> transfer to MDS. Please feel free to call me to discuss this further.
>
> Best regards,
>
> Jodi Pickering
> > etrials, Inc
> > Contracts Management and Proposal Development
> 919.653.2067
> 919.653.2001 (fax)
>
>
>
> -----Original Message-----
> From: Steven.Zweig@mdsps.com [mailto:Steven.Zweig@mdsps.com]
> Sent: Monday, October 14, 2002 10:05 AM

PM3006633989

Source: https://www.industrydocuments.ucsf.edu/docs/gtcj0001

> To: Jodi Pickering
> Cc: Dana Winsted; Anthony.Cavaliere@mdsps.com ; Bob.Lynch@mdsps.com ;
> Fang.Fan@mdsps.com ; kimberly.prchal@mdsps.com ; Robert.Earl@mdsps.com
;
> bettie.l.nelson@pmusa.com ; candace.r.adams@pmusa.com ;
> Hans-Juergen.Roethig@pmusa.com ; Jan.Oey@pmusa.com ;
> mohamadi.sarkar@pmusa.com ; robin.d.kinser@pmusa.com ;
> Shixia.Feng@pmusa.com ; Valerie.A.King@pmusa.com
> Subject: Lab data specifications
>
>
>
> Jody,
>
> The ID variable specifications will need to be consistent across all
data
> sources.
>
> Can you please provide ID variable specifications for the etrials data

> base. This would include name, type (number or character), and
structure
> for the investigator, patient, and visit variables.
>
> Thanks much,
> Steven
>

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